

This rejection is respectfully traversed.

Kimura et al. (U.S. 5,556,858) discloses an ophthalmic suspension containing difluprednate, but Kimura et al. does not disclose an emulsion containing difluprednate, oil, water and an emulsifier.

When compared with the suspension containing difluprednate as disclosed in Kimura et al., the inventive emulsion containing difluprednate exhibited superior delivery to lesions, uniform drug distribution after administration and less discomfort. In addition, the superior delivery to lesions leads to sufficient efficacy achieved with a small dose that suppresses side effects (present specification page 14, line 3 from the bottom, to page 15, line 5).

Particularly in Experimental Example 1 (present specification, pages 11 to 14), the suspension of Kimura et al. and the emulsion of the present invention are compared in terms of intraocular transfer. The formulation of the suspension shown in Table 1 is the same as that in Example 2 of Kimura et al. except that the concentration of difluprednate was set to 0.1 g/100 ml. The results shown in Table 2 reveal that the emulsion of the present invention is superior in intraocular transfer, as evidenced by the amount of the drug transferred into the eye, which was about 2.2 times more than that of the suspension, even when the drug concentration in the composition was half that of the suspension.

To further establish the nonobviousness of the present invention, submitted herewith is the Rule 132 Declaration of K. Haruna presenting comparative test data of the claimed emulsion vs. the reference suspension, wherein the anti-inflammatory actions of both preparations in rat endotoxin-induced uveitis models were compared. As shown in the results reported in the Declaration, the emulsion of the present invention showed an inflammation suppressing effect superior to that achieved by the suspension of Kimura et al.

The emulsion of the present invention is unobviously superior to the suspension in intraocular transfer of the drug and anti-inflammatory action. Such superior effect is not suggested by Kimura et al. Inasmuch as the emulsion of the present invention shows such unexpected superior effect, it is not obvious from Kimura et al.


For the foregoing reasons, it is apparent that the rejection on prior art are untenable and should be withdrawn.

No further issues remaining, allowance of this application is respectfully requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned at the telephone or facsimile number below.

Respectfully submitted,

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